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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/884,715	06/19/2001	Malcolm Richard Boyd	4-31830B	3629

1095 7590 08/23/2005

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CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
MOSHER, MARY	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 08/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/884,715	BOYD, MALCOLM RICHARD	
	Examiner	Art Unit	
	Mary E. Mosher, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *7,9,10,19 and 20* is/are ~~allowed.~~ allowable, but see Interference section of action

6)☒ Claim(s) *8,11-18,21 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 5/27/05, 1/26/06

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application (PTO-152)

6)☐ Other: _____.

DETAILED ACTION

Allowable Subject Matter

The indicated allowability of claims 8, 11-18, 21, 22 is withdrawn after reconsideration of the metes and bounds of the claimed subject matter, and reconsideration of the teachings of the prior art. These rejections have to do with the "prophylaxis" embodiments of the method claims. There is also discussion of the distinctness (or lack thereof) of the instant claims from US Patent 6337324.

Claim Rejections - 35 USC § 112

Claims 8, 11-18, 21, 22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of herpes simplex virus infection, does not reasonably provide enablement for prophylaxis of herpesvirus infection. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. Claim 8, 13, and 16 recite "prophylaxis of a herpes simplex virus infection in a human." Search of prior and subsequent art indicates that famciclovir and penciclovir are capable of preventing HSV-induced disease, but are not capable of preventing infection by HSV. See for example the four abstracts of publications by Thackray et al, indicating that famciclovir inhibits but does not prevent HSV infection in an animal model for viral latency. The specification provides a working example, in an animal model, for treatment of a pre-existing infection. There is no working example demonstrating prevention of infection. Considering the state of the art, the limited teachings in the specification, and the absence of a working example, it is

concluded that undue experimentation would be required to practice "prophylaxis of herpes simplex virus infection" as claimed.

Claim Rejections - 35 USC § 102

Claims 8, 11, 12, 16-18, 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Boker et al (previously cited). Boker et al describes treatment of a human with an immunosuppressant and, at the same time, with oral famciclovir. The reference is silent upon herpesviruses. However, since immunosuppressed patients are at risk for newly-transmitted infections or reactivation of latent infections, the treated person is seen as meeting the requirement for a human in need of prophylaxis of a herpes simplex virus infection. The treatment method taught in the reference inherently constitutes prophylaxis against herpesvirus infection, even though the reference is silent upon the topic of herpesviruses.

Interference

Applicant has indicated by telephone that the preference is to claim subject matter that is patentably distinct from US 6337324, and has submitted amended claims for this purpose.

However, some of the submitted claims are not patentably distinct, for the following reasons. Claims 7, 9, 10, 19, 20 are drawn to compositions "for oral or parenteral administration." Viewing the patent claims in light of the supporting disclosure, the patent states at column 5, lines 47049, that compositions for topical administration include " creams, lotions, gels, ointments, or drops." Applicant's supporting disclosure for oral formulations includes "solutions, syrups, and

suspensions," see page 4 lines 27-29. There does not appear to be any physical or chemical feature that distinguishes between "drops" and "solutions, syrups, and suspensions." Applicant's disclosure of parenteral formulations recites "suspensions, solutions, or emulsions in oily or aqueous vehicles," see page 5 lines 7-9. There does not appear to be any physical or chemical feature that distinguishes between "creams, lotions, gels, ointments" and "emulsions in oily or aqueous vehicles," or between "drops" and "suspensions or solutions."

In regard to methods of use, applicant's claims 8, 13-18, 21 drawn to oral treatment methods are not distinct from the patent claims, because the patent claims include treatment of "mucous membranes." The oral cavity is lined with mucous membranes. It is also an obvious choice for mucous membranes to be treated, since oral herpes infections are well known.

The following types of claims would be distinct from the patent claims:

Pharmaceutical compositions in tablet or capsule form

A unit dosage form comprising a parenteral formlation in a syringe

A parenteral treatment method

A treatment method involving oral administration of composition in tablet or capsule form.

These administration methods are seen as distinct from the patent, because none of these would be appropriate for the topical/mucosal purposes claimed in the patent.

Allowable Subject Matter

Apart from interference issues with US 6337324, claims 7, 9, 10, 19, and 20 remain allowable, as the available prior art does not teach or suggest combining an immunosuppressant in the same composition with famciclovir or penciclovir.

Information Disclosure Statement

The information disclosure statement filed 5/27/2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered, except for the cited U.S. patent.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on M-T and alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

8/21/05

MARY E. MOSHER, PH.D.
PRIMARY EXAMINER